DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

**Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient PPS– to be used for tracking purposes**
**(for the complete application requirements, please see the instructions at http://cms.hhs.gov/providers/hipps/default.asp)**
**Note: The information provided on this tracking form may be made publicly available**

1. Applicant Name: Date:
2. Manufacturer Name:
3. Contact Name:
4. Address:
5. Telephone Number:
6. Email Address:
7. Trade Brand of Technology:
8. Brief Description of Service or Device:

**New Criteria**

9. Date of FDA approval (or expected approval) for the device or service:
10. Was the service or technology considered under FDA priority review?
11. Does the technology have an ICD-9-CM code or is one pending? If yes, please specify.
12. Does the service or technology have a HCPCS code associated with it? If yes, please specify.
13. If the technology is a device, is there an IDE number assigned to the device? If yes, please specify.
14. Have you submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system? If so, when? Have you been approved? If yes, when was your approval?

**Cost Criteria**

15. Affected diagnosis-related groups (DRGs):
16. What is the anticipated volume of this technology (by DRG)?
17. Weighted standard deviation threshold in affected DRGs:
18. What is the anticipated average standardized charge per case involving this new technology?
19. What is the estimated cost per case for the service or technology?
20. Number of cases/patients, distinguishing between Medicare and non-Medicare:
21. Average dosage/number of units and estimated costs for sub-populations:

**Clinical Improvement**

22. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.
    a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

    b. Briefly describe relevant clinical trial(s), including dates and findings:

    c. List of published peer-review articles relevant to the new service or technology:

**INSTRUCTIONS**

**General Information:**

1. Applicant Name.
2. Manufacturer name.
3. Contact name.
4. List address of applicant.
5. List telephone number(s) of all applicable contacts.
6. List email addresses of contact(s).
7. Trade/brand name of the new technology.
8. Provide a brief description of the clinical application of the technology.

**New Criteria Information:**

9. Date of FDA approval (or expected approval) for the service or device.
10. Was the service or device considered under FDA priority review?
11. Provide the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used. If there is no appropriate ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code.
12. Does the service or technology have a HCPCS code associated with it? If yes, please provide this code.
13. Is there an IDE number assigned to the device? If yes, please provide this number.
14. Have you submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system? If so, please tell us when you submitted this application and whether it was approved for pass through payments in the outpatient PPS. If it was approved, please provide the date of approval.

**Cost Criteria Information:**

15. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.
16. What is the anticipated volume of this technology (by DRG)?
17. Please provide the weighted standard deviation threshold in the affected DRGs. In order to calculate this dollar amount, please use Table 10 in the most current inpatient prospective payment system update in the Federal Register to determine the appropriate threshold that the technology would have to meet or exceed in order to qualify. If more than one DRG is affected, the calculation should be determined using a case-weighted mean standardized charge and standard deviation for all of the DRGs to which a

technology is likely to be assigned (based on the number of cases estimated to be assigned to each relevant DRG). The resulting mean standardized charge and standard deviation would then be the threshold amount that the new technology would have to exceed in order to qualify. Table 10 is located at: http://cms.hhs.gov/providers/hipps/50231-50280.pdf.

18. What is the anticipated average standardized charge per case involving this new technology?
19. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)?
20. List the number of patients included in the analysis and distinguish between Medicare and non-Medicare patients.
21. Calculate and list the average dosage or number of units of the new technology that is used per patient (e.g., mL/kg/hr). Also include the estimated costs for sub-populations such as those that will be more reliant on the new technology.

**Clinical Improvement Information:**

22. Provide a brief description of how the new technology meets our substantial clinical improvement criteria.
    a. Brief description of clinical improvement.
    b. Provide a brief description of clinical trial(s) involved with getting the new technology approved for use. If submitting this information to meet the cost criteria, please provide the items listed in the cost criteria above based on these data.
    c. Provide a list of published articles where the new technology is presented.